

GASTROENTEROLOGY PRODUCT HIGHLIGHTS

Celiac disease (CD) is a major public health concern because it affects 1% of the population in certain regions and it is often underestimated. The disease is frequently associated with other autoimmune diseases and can take up to several years before it is properly diagnosed.

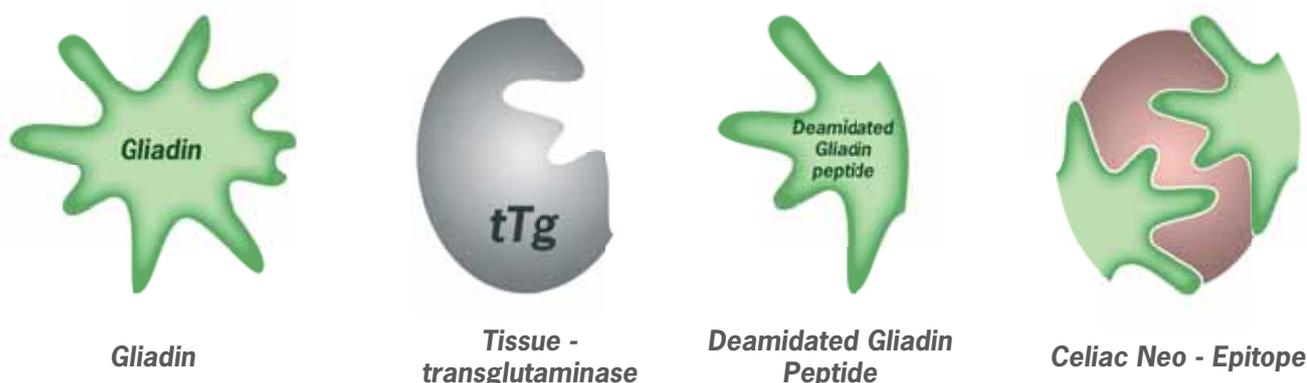
The classic diagnostic tools (tTg, EMA, gliadins) have known limitations and there are several studies reporting that even with human recombinant tTg assays, there are still cases of sero-negative celiac disease patients which may go unnoticed in a laboratory diagnosis, based on tTg antibodies alone.

AESKU.DIAGNOSTICS has placed huge efforts on the research, development, production and optimization of new markers for CD, to help the laboratories shortening the time to diagnosis. Since it has an important impact on the health improvement status of the patients.

In 2001, AESKU.DIAGNOSTICS presented a new important antigen strategy for celiac detection:
The AESKU.DIAGNOSTICS Celiac neo-epitopes used in our **AESKULISA® tTg New Generation** kits.

The new epitopes are produced under controlled conditions by the modification and crosslink reaction of specially developed gliadin peptides with tissue transglutaminase. Thereby leading to an antigen which is extrinsic to the immune system and is currently in discussion to be one of the causes for the autoimmune reaction in celiac disease.

Different epitopes used in Celiac disease Diagnostics:

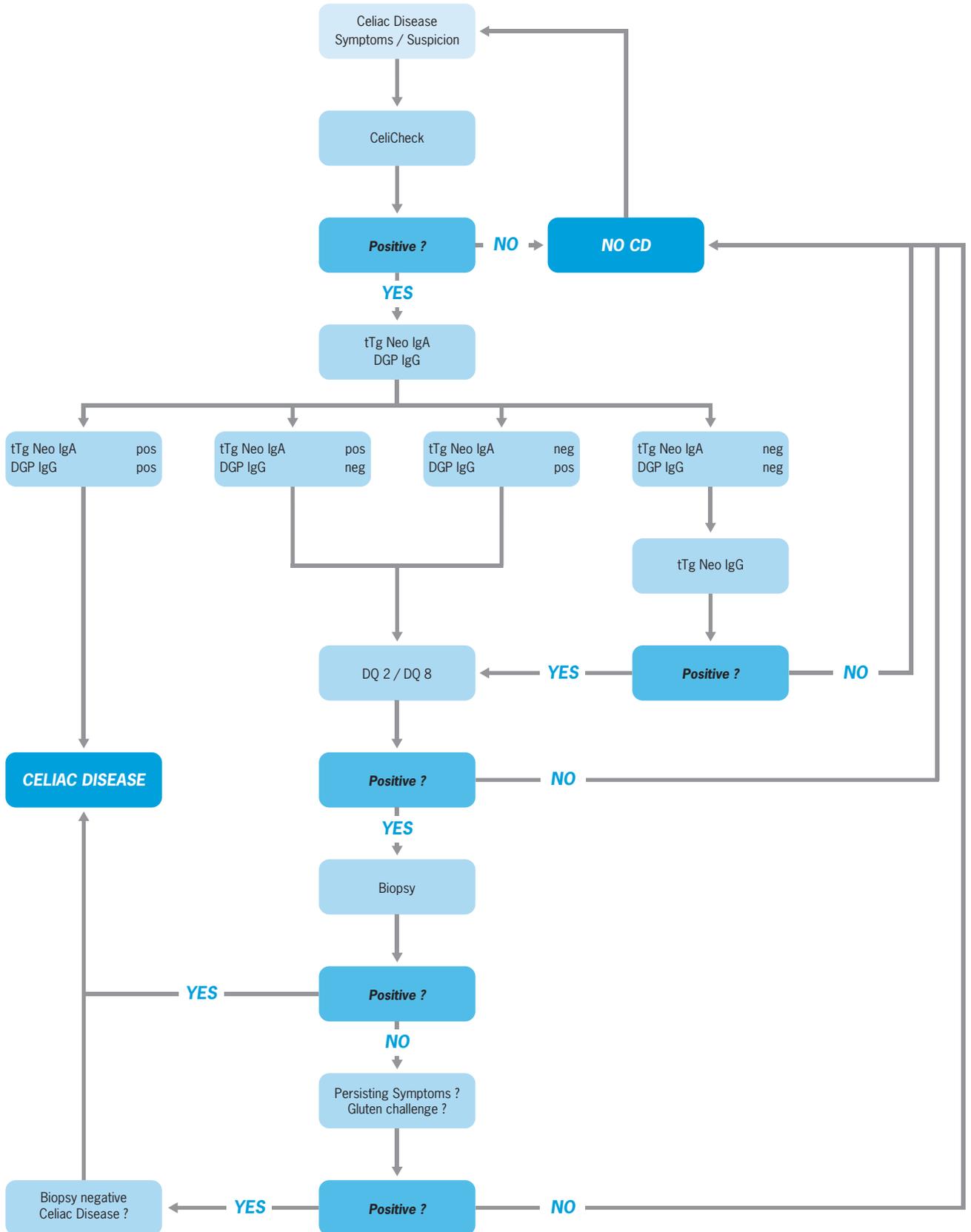


Over the years, different studies have shown that the AESKULISA® tTg New Generation is the perfect Celiac disease screening tool that:

- Can be used to screen both adult and pediatric populations.
- Can be used to screen IgA deficient patients (Celiceck New Generation screens for IgA+IgG).
- Proved to be more sensitive than the classical markers (tTg / EMA).
- Can detect tTg seronegative celiac disease patients.
- Correlates with the classical markers (tTg / EMA) in the active phase of the disease but can detect antibodies up to 15 months before tTg or DGP (predictive).
- Has a better correlation with the mucosal damage (Marsh score) in comparison to the classical markers.

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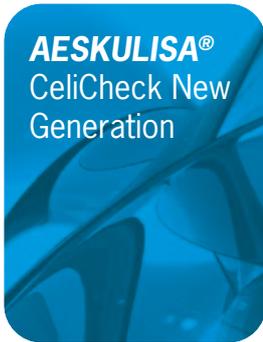
The following diagnostic flowchart for CD is proposed by AESKU.DIAGNOSTICS:



A definite clinical diagnosis should not be based on the results of the performed tests alone, but should be made by the physician after all clinical and laboratory findings have been evaluated. The diagnosis is to be verified using different diagnostic methods.

GASTROENTEROLOGY

REF 3510

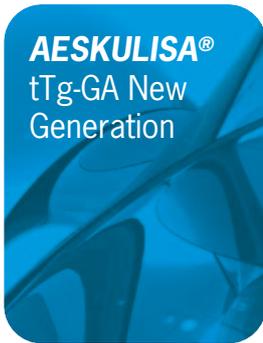


Conjugate:
anti-IgA/G-HRP
Equivocal Zone:
16 - 24 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-Check

Antigens coated:
Recombinant human tissue transglutaminase (neo-epitopes), cross-linked with specific peptides of gliadin

Enzyme-linked immunoassay (ELISA) for the combined quantitative and qualitative determination of IgA and IgG autoantibodies to neo-epitopes of tissue transglutaminase (tTg) in human serum

REF 3516

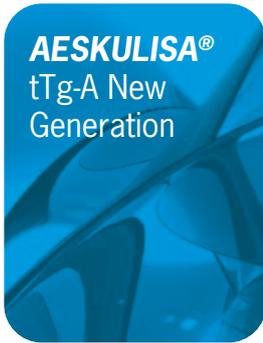


Conjugate:
anti-IgA-HRP + anti-IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-AG

Antigens coated:
Recombinant human tissue transglutaminase (neo-epitopes), crosslinked with specific peptides of gliadin

Enzyme-linked immunoassay (ELISA) for the separate quantitative and qualitative determination of IgA and/or IgG antibodies to neo-epitopes of tissue transglutaminase (tTg) in human serum

REF 3503

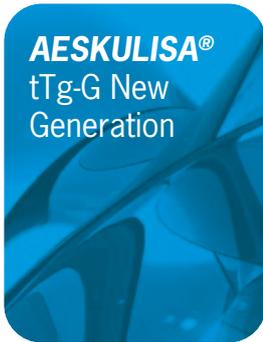


Conjugate:
anti-IgA-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-A

Antigens coated:
Recombinant human tissue transglutaminase (neo-epitopes), crosslinked with specific peptides of gliadin

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgA autoantibodies to neo-epitopes of tissue transglutaminase (tTg) in human serum

REF 3504

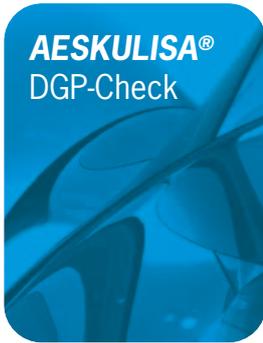


Conjugate:
anti-IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Recombinant human tissue transglutaminase (neo-epitopes), crosslinked with specific peptides of gliadin

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to neo-epitopes of tissue transglutaminase (tTg) in human serum

REF 3515



Conjugate:
anti-human IgA/G-HRP
Equivocal Zone:
16 - 24 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-Check

Antigens coated:
Deamidated gliadin-peptides

Enzyme-linked immunoassay (ELISA) for the combined quantitative and qualitative determination of IgA and IgG autoantibodies to deamidated gliadin-peptides in human serum

GASTROENTEROLOGY

REF 3517



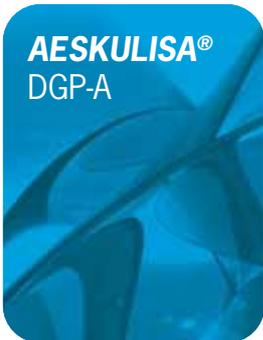
AESKULISA®
DGP-GA

Conjugate:
anti-human
IgG-HRP + IgA-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-GA

Antigens coated:
Deamidated gliadin-peptides

Enzyme-linked immunoassay (ELISA) for the separate quantitative and qualitative determination of IgA and/or IgG antibodies to deamidated gliadin-peptides in human serum

REF 3513



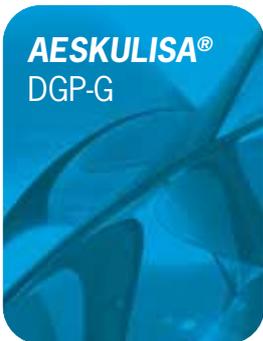
AESKULISA®
DGP-A

Conjugate:
anti-human IgA-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0-300 U/ml
Kit Configuration:
Single-A

Antigens coated:
Deamidated gliadin-peptides

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgA autoantibodies to deamidated gliadin-peptides in human serum

REF 3514



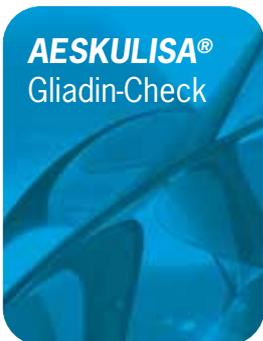
AESKULISA®
DGP-G

Conjugate:
anti-human IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0-300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Deamidated gliadin-peptides

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies against deamidated-gliadin-peptides in human serum

REF 3500



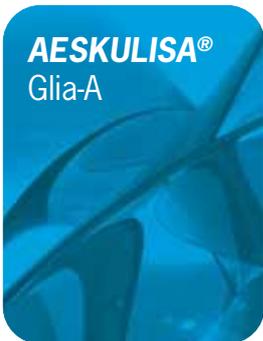
AESKULISA®
Gliadin-Check

Conjugate:
anti-human
IgA/G-HRP
Equivocal Zone:
16 - 24 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-Check

Antigens coated:
Purified alpha-gliadin

Enzyme-linked immunoassay (ELISA) for the combined quantitative and qualitative determination of IgA and IgG antibodies to alpha-gliadin in human serum

REF 3501



AESKULISA®
GliA

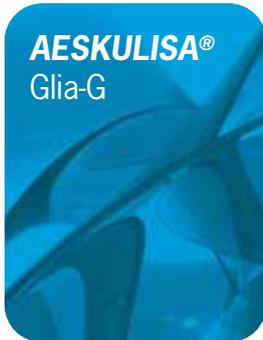
Conjugate:
anti-human IgA-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0-300 U/ml
Kit Configuration:
Single-A

Antigens coated:
Purified alpha-gliadin

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgA antibodies to alpha-gliadin in human serum

GASTROENTEROLOGY

REF 3502



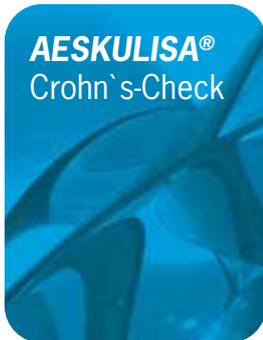
AESKULISA®
GliA-G

Conjugate:
anti-human IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0-300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Purified alpha-gliadin

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG antibodies to alpha-gliadin in human serum

REF 3509



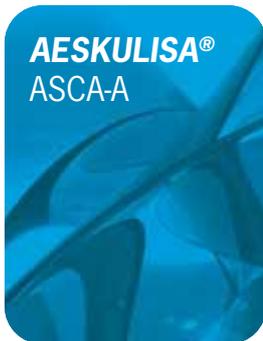
AESKULISA®
Crohn`s-Check

Conjugate:
anti-human IgA/G-HRP
Equivocal Zone:
16 - 24 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-Check

Antigens coated:
Purified mannan of Saccharomyces cerevisiae

Enzyme-linked immunoassay (ELISA) for the combined quantitative and qualitative determination of IgA and IgG antibodies to cell wall proteoglycans of Saccharomyces cerevisiae in human serum

REF 3507



AESKULISA®
ASCAA

Conjugate:
anti-human IgA-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-A

Antigens coated:
Purified mannan of Saccharomyces cerevisiae

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgA antibodies to cell wall proteoglycans of Saccharomyces cerevisiae in human serum

REF 3508



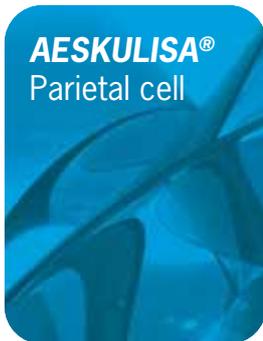
AESKULISA®
ASCA-G

Conjugate:
anti-human IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Purified mannan of Saccharomyces cerevisiae

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG antibodies to cell wall proteoglycans of Saccharomyces cerevisiae in human serum

REF 3511



AESKULISA®
Parietal cell

Conjugate:
anti-human IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Native H+/K+ ATPase from porcine gastric mucosa

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies against parietal cells in human serum

REF 3512

AESKULISA®
Intrinsic Factor

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Recombinant human intrinsic factor

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to intrinsic factor in human serum

AESKUBLOTS®

The **AESKUBLOTS®** test line represents a variety of different immunoblots for efficient profile testing of autoimmune and infectious diseases.

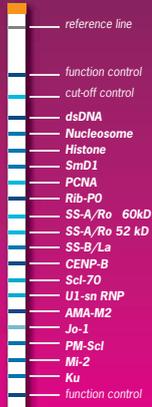
Coated with a selected panel of specific antigens on one test strip, **AESKUBLOTS®** provide a complete diagnostic overview in a single test and are suitable for screening of autoimmune diseases as well as cost-effective differential diagnosis.

For an easy automated processing the HELMED® BLOT processor can be used. For an easy semi-quantitative and automatic interpretation of AESKUBLOTS®, AESKU.SYSTEMS provides a dedicated evaluation software: AESKU.SCAN®.



REF 4001

ANA-17 Pro



AESKUBLOTS® ANA-17 Pro

24 tests/kit

Conjugate: anti-human IgG-HRP

Color-coded (orange) test strips with cut-off and positive control

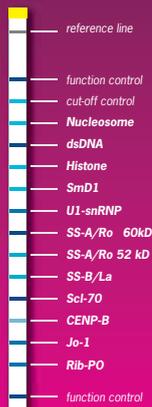
Immunoblot for the qualitative detection of IgG antibodies against:

dsDNA, nucleosomes, histones, SmD1, PCNA, Rib-PO, SS-A/Ro60kD, SS-A/Ro52kD, SS-B/La, CENP-B, Scl-70, U1-sn RNP, AMA-M2, Jo-1, Pm-Scl, Ku and Mi-2 in human serum.

AESKUBLOTS® ANA-17 Pro is used for the differential diagnosis of systemic rheumatic diseases. Detection of autoantibodies in **AESKUBLOTS®** with the corresponding specific antigens allows an easier and more reliable differentiation of specific ANAs (anti-nuclear antibodies). The ANAs included occur in active and inactive systemic lupus erythematosus (SLE), mixed connective tissue diseases (MCTD), scleroderma, Sjogren's syndrome, primary biliary cirrhosis (PBC) and polymyositis. **ANA-17 Pro** antigens are fitted on the test strip according to their relevance for the individual autoimmune disease (SLE, Sjogren's syndrome, CREST syndrome, scleroderma, MCTD, myositis, and PBC) allowing easier interpretation.

REF 4000

ANA-12 Pro



AESKUBLOTS® ANA-12 Pro

24 tests/kit

Conjugate: anti-human IgG-HRP

Color-coded (yellow) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:

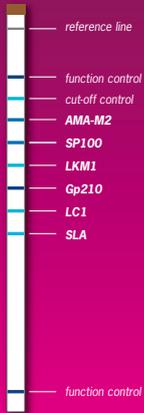
nucleosomes, dsDNA, histones, SmD1, U1-snRNP, SS-A/Ro60kD, SS-A/Ro52kD, SS-B/La, Scl-70, CENP-B, Jo-1 and ribosomal P protein (Rib-PO) in human serum.

AESKUBLOTS® ANA-12 Pro is used for the differential diagnosis of systemic rheumatic diseases. Detection of autoantibodies in **AESKUBLOTS®** with the corresponding specific antigens allows an easier and more reliable differentiation of specific ANAs (anti-nuclear antibodies). The ANAs included occur in active and inactive systemic lupus erythematosus (SLE), mixed connective tissue diseases (MCTD), scleroderma, Sjogren's syndrome and polymyositis.

AESKUBLOTS®

REF 4004

Liver Pro



AESKUBLOTS® Liver Pro

24 tests/kit

Conjugate: anti-human IgG HRP

Color-coded (brown) test strips with cut-off and positive control

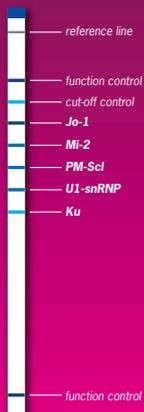
Immunoblot for the qualitative detection of IgG antibodies against:

AMA-M2, Sp100, LKM1, gp210, LC1 and SLA in human serum.

AESKUBLOTS® Liver Pro is used as an aid in the diagnosis of autoimmune liver diseases. The most important autoimmune liver diseases are autoimmune hepatitis (AIH) types 1-3, primary biliary cirrhosis (PBC) and a combination of both diseases (immunocholangiopathy). AIH is a chronic, progressive liver disease of unknown cause, which responds well to immunosuppressive therapy, however, if untreated it has a poor prognosis. PBC is a chronic inflammatory disease of the small and medium-size bile ducts. Undetected it can lead to liver cirrhosis. An early and reliable diagnosis is therefore of great importance.

REF 4003

Myositis Pro



AESKUBLOTS® Myositis Pro

24 tests/kit

Conjugate: anti-human IgG HRP

Color-coded (blue) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:

Jo-1, Mi-2, Pm-Scl, U1-snRNP and Ku in human serum.

AESKUBLOTS® Myositis Pro is designed to help in the diagnosis of poly- and dermatomyositis, as well as myositis-associated autoimmune diseases. Autoimmune myositis represents a heterogeneous group of acquired muscle diseases. Their main clinical and morphological characteristics are muscle weakness and inflammatory infiltration of skeletal muscles.

REF 4002

Vasculitis Pro



AESKUBLOTS® Vasculitis Pro

24 tests/kit

Conjugate: anti-human IgG HRP

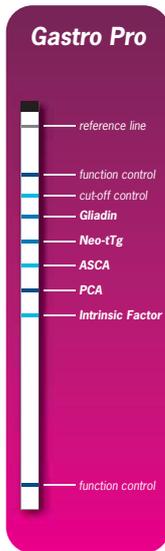
Color-coded (purple) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:

PR3, MPO and GBM in human serum.

AESKUBLOTS® Vasculitis Pro is used for the differential diagnosis of autoimmune vasculitis. Antibodies against proteinase 3 (PR3) and myeloperoxidase (MPO) belong to the group of anti-neutrophil cytoplasmic antibodies (ANCA), which have been described as important markers in the differential diagnosis of autoimmune vasculitis. Anti-PR3 antibodies represent specific serological markers for granulomatosis with polyangiitis (Wegener's) and could play a role in pathogenesis. Anti-MPO antibodies occur in idiopathic and vasculitis-associated rapidly progressive glomerulonephritis, they are found in up to 70% of microscopic polyangiitis, and up to 5 - 50% in the Churg-Strauss syndrome. Serological detection of circulating antibodies against glomerular basement membrane in the glomeruli (GBM) is the method of choice in diagnosis of Goodpasture's syndrome.

REF 4005



AESKUBLOTS® Gastro Pro

24 tests/kit

Conjugate: anti-human IgA/IgG HRP

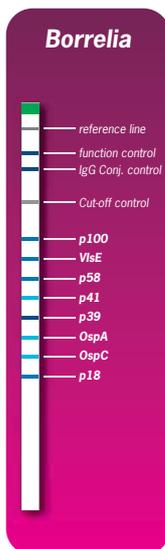
Color-coded (black) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgA and IgG antibodies against:
Gliadin, Neo-tTg, mannan (ASCA), parietal cells and Intrinsic factor-antigen.

AESKUBLOTS® Gastro Pro is designed to assist in the diagnosis of celiac disease, pernicious anemia and Crohn's Disease. Each section of the gastro-intestinal tract can be affected by autoimmune gastrointestinal diseases. Disease is often diagnosed years after occurrence of initial symptoms and outcome is severe in many cases.

Celiac patients often have an IgA deficiency. In order to avoid false-negative results, **AESKUBLOTS® Gastro Pro** detects IgA and IgG antibodies.

REF 4006



Borrelia

AESKUBLOTS® Borrelia-G

24 tests/kit

Conjugate: anti-human IgG HRP

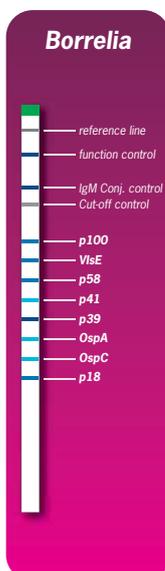
Color-coded (green) test strips with cut-off, positive and conjugate control

Immunoblot for the qualitative detection of specific **IgG** against *Borrelia burgdorferi* in human serum.

The assays provide tools for confirmation of positive and borderline ELISA (**AESKULISA® Borrelia-G**) results, and are in accordance with the two stage testing procedure recommended by the German Society for Hygiene and Microbiology (DGHM).

Lyme disease is a multisystemic disease caused by infection with the spirochete *Borrelia burgdorferi*, transmitted in Europe mainly by *Ixodes ricinus* (sheep tick). The antigens coated on the test strips are: p100, VlsE, p58, p41, p39, OspA, OspC and p18.

REF 4007



Borrelia

AESKUBLOTS® Borrelia-M

24 tests/kit

Conjugate: anti-human IgM HRP

Color-coded (green) test strips with cut-off, positive and conjugate control

Immunoblot for the qualitative detection of specific **IgM** against *Borrelia burgdorferi* in human serum.

The assays provide tools for confirmation of positive and borderline ELISA (**AESKULISA® Borrelia-M**) results, and are in accordance with the two stage testing procedure recommended by the German Society for Hygiene and Microbiology (DGHM).

Lyme disease is a multisystemic disease caused by infection with the spirochete *Borrelia burgdorferi*, transmitted in Europe mainly by *Ixodes ricinus* (sheep tick). The antigens coated on the test strips are: p100, VlsE, p58, p41, p39, OspA, OspC and p18.